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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

FDA Docket No. 2003N-0076 Food Labeling: Trans Fatty Acids in Nutrition Labeling; Consumer Research to Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements: Reopening of the Comment Period. Advance notice of proposed rulemaking 69 FR 9559-9560 (March 1, 2004)

Dear Sir/Madam:

Archer Daniels Midland Company (ADM) is pleased to provide FDA with comments regarding the Advance Notice of Proposed Rulemaking (ANPR) for **Food Labeling: Trans Fatty Acids in Nutrition Labeling; Consumer Research to Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements: Reopening of the Comment Period**. ADM is a world leader in agricultural processing and is one of the world's largest processors of soybeans, corn, canola, wheat and cocoa. ADM is also a leader in producing vegetable oils as well as soy meal, ethanol, high fructose corn syrup and flour. In addition, ADM is building a position in value-added areas including specialty food ingredients, bioproducts and nutraceuticals (such as vitamin E, sterols, and soy isoflavones)

ADM welcomes the opportunity to be a participant in this rulemaking process for labeling of *trans* fatty acids and supports the Agency's efforts to develop a process that facilitates the communication of truthful and non-misleading information about dietary fat to consumers. We support the development of a regulatory process by which scientifically-based information about the nutritional value of dietary fats and oils can be communicated to the consumer. We are providing our general comments and recommendations as follows:

I. ADM supports the adoption of a separate Daily Value (DV) for saturated fat and *trans* fat. Using recommendations for Therapeutic Lifestyle Changes described in The National Cholesterol Education Program Adult Treatment Panel III (See <http://www.nhlbi.nih.gov/guidelines/cholesterol/atp3full.pdf>, Table V.2-1), we support establishing a new DV of 7% of total energy for saturated fat which translates to 16 grams based on a 2000 calorie diet. Using recently published data examining intake of *trans* fatty

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acids in the U.S. population² (See Allison, D. B., S. K. Egan, et al. (1999). "Estimated intakes of trans fatty and other fatty acids in the US population." *J Am Diet Assoc* 99(2): 166-74), we support a new adequate intake (AI) of $\leq 3\%$ of total energy for *trans* fatty acids which translates to 7 grams based on a 2000 calorie diet.

II. ADM supports the formalization of labeling saturated fatty acids according to their biological activity in terms of effecting serum cholesterol levels. Only two choices exist for food manufacturers seeking *trans* fat alternatives where solid fat is required: 1) Solid fats derived from imported tropical oil sources or 2) Solid fats containing stearic acid derived from fully hydrogenated vegetable oil. Individual saturated fats have differing effects on serum cholesterol levels. As a result, the nutritional differences between various saturated fatty acids must not be overlooked when estimating their potential impact on public health. The following information (Table 1) summarizes opinions from the DRI Panel on Macronutrients, WHO/FAO Expert Consultation and American Heart Association on differences between saturated fatty acids with regard to effect on serum cholesterol levels or risk of cardiovascular disease.

Table 1. Impact of Saturated Fatty Acids on Serum Cholesterol Levels or Heart Disease Risk: Opinions of Authoritative Scientific Organizations

Saturated Fatty Acid	Impact on Serum Cholesterol or CVD Risk		
	DRI ¹	WHO ²	AHA ³
Stearic	Neutral	Neutral	Neutral
Palmitic and myristic	Increases	Increases	Increases

¹Total and LDL cholesterol levels in Institute of Medicine (2002). *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients)*, Chapter 8, National Academy Press, Washington, D.C., p. 383

²CVD risk in Joint WHO/FAO Expert Consultation (2003). *Diet, Nutrition and the Prevention of Chronic Diseases*, World Health Organization, Geneva. WHO Technical Report Series 916, pp. 147-148

³Total and LDL cholesterol levels in *Circulation* 2001; 103:1034-1039.

Uniformly in these opinions, stearic acid clearly is viewed as neutral towards serum cholesterol levels while palmitic and myristic acids predominantly found in tropical oils are viewed consistently as hypercholesterolemic. As a result, ADM proposes the following labeling guidelines for saturated fat:

- A. In the Nutrition Facts panel, establish a separate line item for "Net Saturated Fat" which would equate to the quantitative value of "Total fat" minus the quantitative

value of "Stearic acid." However, at a minimum, promotion of "Net Saturated Fat" for back panel information should be encouraged.

- B. In the Ingredients list, allow the adoption/utilization of the term "High stearic vegetable oil" in place of "Hydrogenated vegetable oil" for fully hydrogenated vegetable oil since the term "hydrogenation" is often confused by consumers to infer the presence of *trans* fat when, in fact, fully hydrogenated vegetable oil would contain virtually no *trans* fatty acids.

The addition of *trans* fatty acid content to the Nutrition Facts Panel was driven by the effect of *trans* fatty acids on serum cholesterol levels. This precedent of listing a nutrient on food labels due to its biological activity should be equally applied to individual saturated fatty acids. The adoption of these proposed labeling guidelines distinguishing individual saturated fatty acids based on their serum cholesterol activity will provide incentives for food processors to deliver products with enhanced nutritional characteristics with respect to inclusion of *trans* fat alternatives and will assist consumers in choosing products with superior nutritional and health profiles.

Summary

ADM appreciates the opportunity to comment on this important FDA initiative to develop guidelines for labeling *trans* fatty acids and promote the development of alternatives to *trans* fat that deliver positive nutritional attributes. We encourage the development of labeling guidelines that are consistent with the existing science of dietary fats and health, and promote the utilization of *trans* fat alternatives with positive nutritional and health attributes. ADM strives to provide safe and beneficial food ingredients to the food industry for the development of healthy and nutritious products for consumer marketplace.

Sincerely,

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